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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/628,308

07/29/2003

Julie Hazel Campbell

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EXAMINER

GHERBI, SUZETTE JAIME J

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

11/16/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/628,308

Applicant(s)

CAMPBELL ET AL.

Examiner

Suzette J. Gherbi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 35-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## DETAILED ACTION

Applicant remarks dated 7/26/07 have been received in application serial number 10/628,308. All comments have been taken in consideration.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35-56 are rejected under 35 U.S.C. 102(b) as being anticipated by or in the alternative, under 35 U.S.C. 103(a) as obvious over Ketharanathan (4,319,363).

Ketharanathan discloses fabricating a surgical graft produced by implanting a rod or tube in a host and growing collagenous tissue forming a coherent tubular wall of collagenous tissue. The implant is removed from the host and the collagenous tissue is removed from the rod or tube, treated and used as a vascular prosthesis.

Vascular prosthesis suitable for use as a surgical graft is produced by implanting a rod or tube in a living host animal such as a sheep and allowing collagenous tissue to grow on the implant to form a coherent tubular wall of collagenous tissue. The implant is subsequently removed and the tubular wall of collagenous tissue is stripped from the rod or tube and tanned in glutaraldehyde to serve as a vascular prosthesis.

While Ketharanathan does not specifically recite myofibroblast forming on the mold support it is well known in the art that myofibroblast cells are precursors to collagen tissues especially type 1 collagen. (see for example Young et al. 5,827,735; 3:61-67, 4:1-8 which discusses the correlation between myofibroblast cells and collagen).

Claims 36 and 37, as broadly worded read on the removal and separation of the implant from the rod/tube of Ketharanathan.

Claim 39, the rod/tube is placed within a cavity of the body by surgical implantation.

Claims 45-48 the tissue formed on the device would be tubular in form and could be used in the manner as set forth in claims 45-48.

Claims 50-52, the tissue is autologous and the rod can be placed in the peritoneal cavity.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ketharanathan as applied to claim 35 above, and further in view of DeVore et al. 4,713,446.

Claim 40, to prevent adhesion of tissue to the collagen mesothelial cells may cover the tissue of Ketharanathan as taught by Devore et al. see 16:20+

In order to prevent adhesion formation between two endothelial or connective tissue membranes certain collagen solutions could be implanted between mesothelial pericardial and pleural sheets.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ketharanathan in view of Tranquillo et al. 6,666,886.

The use of biodegradable matrix for growing new tissue thereon is taught by Tranquillo et al. Such use in place of non-resorbable matrix offers the ability for ease of removal of the implant after a predetermined period of time without causing trauma to the neo-tissue that comprises the implant.

Claims 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ketharanathan as applied to claim 35 above and further in view of Sparks 3,938,524. Here, Sparks teaches materials used for molding rod/tubes.

Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ketharanathan as applied to claim 35 supra and further in view of either of Dardik et al. 3,894,530 or Bruchman et al. 5,584,876.

The use of freezing or lyophilizing tissue to preserve and store the tissue prior to implantation is well known in the art as taught by each of Dardik et al. and Bruchman et al. To use freezing techniques to preserve and store the tissue derived from Ketharanathan prior to implantation would have been obvious to one with ordinary skill in the art from the teachings.

### ***Allowable Subject Matter***

Claims 54-56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Response to Arguments***

Applicant's arguments filed 7/26/07 have been fully considered but they are not persuasive. Applicant contends that the rod/tube of Ketharanathan is placed in the body and not in a body cavity on page 2 of remarks. The examiner does not agree because applicant's specification does not define the "body cavity" but states that the rod/tube is for vascular grafting. Ketharanathan device is for the same purpose and that is for a vascular implant. Although Ketharanathan does not specifically state that the device is implant inside the vasculature (rather implanted in the body) it is obvious if not inherent

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that the vasculature is within the body cavity. Nevertheless as broadly interpreted the body in and of itself is a cavity (as applicant has not defined a specific place).

Applicant further contends that Ketharanathan implants are most probably formed by skin fibroblast (the examiner could not find this passage). This is an assertion on the applicant's part. Ketharanathan's device is capable of forming type 1 collagen from the precursor cells of myofibroblast.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

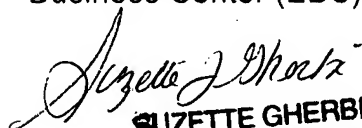
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J-J Gherbi whose work schedule is Maxi-Flex off every other Friday and whose telephone number is 571-272-4751.

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The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**SUZETTE GHERBI**  
**PRIMARY EXAMINER**  
**TECHNOLOGY CENTER 3700**

12 November 2007